

Sunset Public Hearing Questions for  
**Genetics Advisory Committee**  
Created by Section 68-5-503, *Tennessee Code Annotated*  
(Sunset termination June 2013)

- 1. Provide a brief introduction to the Genetics Advisory Committee, including information about its purpose, statutory duties, staff, and administrative attachment. Also describe the Department of Health's Genetics Program, its major activities, and its staffing.**

**Genetics Advisory Committee**

Statute: TCA 68-5-503

Purpose and Duties: The Genetics Advisory Committee is made up of health care professionals from genetics, endocrinology, hematology, pulmonology, cardiology, and sickle cell centers across Tennessee. Their main purpose is to advise the Department of Health on newborn screening and follow-up and offer recommendations to improve services to individuals born with genetic conditions in our state. They recommend changes to the newborn screening panel and the screening and follow-up protocols to assure that all babies born in Tennessee with genetic conditions are identified and provided with appropriate follow-up and treatment in a timely manner, using the latest evidenced-based approach.

Membership: By law, the committee shall be composed of one (1) representative from each regional genetic center and each regional sickle cell center, at least two (2) members at large, and the chief medical officer for the state who may appoint a designee.

**State Genetics Program**

Established by Statute: TCA 68-5-401-404 and 501-505

Purpose: The Department of Health Genetics Program, established in 1968, tests every baby born in Tennessee for 29 of the 31 core conditions and 24 of the 26 secondary conditions recommended for screening by the Secretary's Committee on Heritable Disorders in Newborns and Children (U. S. Department of Health and Human Services). These include phenylketonuria (PKU), galactosemia, hypothyroidism, congenital adrenal hyperplasia, hemoglobinopathies, and many others. In addition, Tennessee tests for four (4) additional conditions not on the Secretary's list<sup>1</sup>. Some of these conditions are life threatening if not caught within the first week of life. The metabolic screening tests are conducted at the State Laboratory, while the hearing screening and newly added pulse oximetry

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<sup>1</sup> The four (4) additional conditions that are not on the Secretary of Health and Human Service's Recommended Panel are all amino acid deficiencies: (1) Carbomoyl Phosphate Synthetase I Deficiency; (2) Hyperornithinemia; (3) Nonketotic Hyperglycemia; and (4) Ornithin Transcarbamylase Deficiency.

are conducted at the birthing facility. Follow-up staff within Maternal and Child Health Section of the Division of Family Health and Wellness notifies the infants' primary care providers and the Tertiary Care Centers (Genetics, Hematology, Pulmonary, etc.) of any screening results which are positive or suspected and need additional testing and/or confirmation. Staff track the cases to assure that all infants needing additional testing and/or follow-up are appropriately receiving care. Staff from the follow-up unit and from the State Laboratory work closely to monitor and improve the newborn screening system in Tennessee. In addition, staff track hearing screening results reported to the State either on the newborn screening laboratory form or on the hearing screening form. By statute, all birthing facilities are required to test newborns for hearing.

The program contracts with five(5) genetic centers and four(4) sickle cell centers across the state to provide diagnostic and follow-up services for infants (and their families) identified through the Newborn Screening Program. The program also contracts with Family Voices and the University of Tennessee at Knoxville for assistance in tracking newborns with possible hearing loss and for working with providers and with families of children with possible hearing loss.

Staffing: Staff responsibility for the Genetics Advisory Committee rests with the Division of Family Health and Wellness/Maternal and Child Health Section within the Department of Health. No staff is solely dedicated to the Committee. For the program, there are five(5) nurses, one program director, and two administrative services assistants providing follow-up for newborn screening and working with the Committee. Responsibility for the oversight of the program rests with Director of the Division of Family Health and Wellness.

**2. Provide a list of current members of the committee and describe how membership complies with Section 68-5-503, *Tennessee Code Annotated*. Who appoints members? Are there any vacancies on the committee? If so, what steps have been taken to fill the vacancies?**

The committee membership complies with requirements set forth in TCA 68-5-503. In addition to the directors from the genetics and sickle cell centers, members include a consumer/parent, neonatologist, pulmonologist, endocrinologist, and pediatric cardiologist. Currently, there are no vacancies on this committee. When a vacancy occurs, names are submitted to the Commissioner for appointment to the committee. The membership list is attached. (NOTE: The official list is being updated and not yet officially finalized. The member list attached, May 2011, lists 15 total members and is current except for the newest member, a pediatric cardiologist, Dr. Jean Ballweg, added February 2012. As of February 2012, the Committee membership total is 16.)

3. **Does the committee include a public/ citizen member? A member who is 60 years of age or older? A member of a racial minority? A member who is female?**

The Genetics Advisory Committee has one member who is a parent/consumer as well as members who are over 60 years of age, members of racial minorities, and female members.

4. **How many times did the committee meet in fiscal years 2011 and 2012, and how many members were present at each meeting?**

The Genetics Advisory Committee met twice in each of the fiscal years 2011 and 2012.

**Schedule and Attendance – Genetics Advisory Committee**

<b>Date</b>	<b>Members Present</b>	<b>Guests &amp; Staff Present</b>
December 2, 2010	13	22
May 5, 2011	14	26
October 20, 2011	13	34
May 3, 2012	14	38

5. **What per diem or travel reimbursement do members of the committee receive? How much was paid to committee members during fiscal years 2011 and 2012?**

Members receive no compensation but can be reimbursed for travel expenses incurred for attendance at the committee meetings.

Travel expenses paid, FY 2011 = \$536.36

Travel expenses paid, FY 2012 (July 1, 2011 – March 31, 2012) = \$ none

6. **What were the committee's revenues (by source) and expenditures (by object) for fiscal years 2011 and 2012? What were the Genetics Program's revenues and expenditures for the same period?**

The Genetics Advisory Committee generates no revenues. The only expenditures for the committee are for travel to the meetings.

Total expenditures and revenues for the State Genetics Program are as follows; the data include laboratory newborn screening, newborn metabolic screening follow-up, and newborn hearing screening follow-up:

<b>Fiscal Year</b>	<b>Revenues</b>	<b>Expenditures</b>
2011	\$7,905,634.37	\$6,847,265.57
2012*	\$6,877,408.10	\$5,169,502.99

\*NOTE – FY 2012 financial information is for the time frame July 1, 2011 – March 31, 2012.

- 7. Is the committee subject to Sunshine law requirements (Section 8-44-101 et seq., *Tennessee Code Annotated*) for public notice of meetings, prompt and full recording of minutes, and public access to minutes? What procedures does the committee have for informing the public of its meetings and making its minutes available to the public?**

The committee is subject to Sunshine law requirements. A meeting notice is forwarded to the Department's Public Information Officer by the 15<sup>th</sup> day preceding the meeting, which includes the date, place, and time of the meeting as well as major agenda items to be discussed. All meeting notices are posted in the month prior to the meeting on the State of Tennessee web site (tn.gov) on the Public Participation Calendar. The minutes are distributed to members, guests, and staff, are kept on file in the program office, and are available to anyone upon request.

- 8. Describe the nature and extent of the committee's activities and any major accomplishments of the past two years.**

All newborns in Tennessee are screened in accordance with the screening panel established by the Department (with assistance and advice from the Genetics Advisory Committee).

During 2011, the Committee recommended revised guidelines for screening very low birth weight (less than 1,500 grams) infants to reduce false negatives and identify congenital hypothyroidism following new evidence in the medical literature. In addition, the GAC recommended adding pulse oximetry screening for all newborns born in Tennessee to screen for seven (7) critical congenital heart diseases after reviews by a workgroup including regional pediatric cardiologists. These two new recommendations have been forwarded to the Commissioner for review and approval prior to implementation.

Since 2010, a Committee work group has been assisting the Department in monitoring testing methodology for possible screening for severe combined immunodeficiency disease (SCID).

Currently, (in 2012) the GAC continues to develop a plan for screening infants for critical congenital heart disease across the state. An established work group of experts is discussing plans for implementation, coordinating with the Perinatal Advisory Committee, investigating screening in other states, and drafting materials and protocols with the Newborn Follow-up Staff.

Every year, periodic newsletters are electronically sent (and posted on the newborn screening web site) to health care providers statewide with the latest information on

screening and follow-up. Advisory committee members frequently provide information and articles for the newsletters.

Finally, and most significantly, members of the Genetics Advisory Committee are instrumental in advising on protocols as well as providing input to the laboratory staff regarding adjustments in cutoff values for screening tests for existing and new diseases.

**9. Does the committee have policies in place to address potential conflicts of interest by committee members, program staff, or other state employees who work with the committee or program in any capacity?**

All state employees are required to sign a conflict of interest statement which is kept in the personnel files. Committee members are requested to sign the Department's conflict of interest policy for committees; copies are kept on file in the program office.

**10. Describe any items related to the committee that need legislative attention and your proposed legislative changes.**

No legislative action is being proposed. The work of the GAC is to inform the Commissioner and the Tennessee Department of Health on any need or advantage for legislation as diseases are added to the national Recommended Universal Screening Panel (RUSP) from the U.S. Department of Health and Human Services.

**11. Should the committee be continued? To what extent and in what ways would the absence of the committee affect the public health, safety, or welfare?**

Unequivocally, the Genetics Advisory Committee should be continued. Expertise of Committee members is critical to maintaining and regularly updating the program and services offered to the citizens of the state. Public health, safety and welfare regarding state action to address genetic conditions are dependent on the knowledge, expertise and familiarity with emerging research that our state's leaders in genetics provide. Program effectiveness would be compromised significantly without the professional guidance provided by content experts on this committee and could lead to harm to the most vulnerable and newest citizens of Tennessee.

**12. Please list all committee programs or activities that receive federal financial assistance and, therefore are required to comply with Title VI of the Civil Rights Act of 1964. Include the amount of federal funding received by program/activity.**

The Committee receives no federal assistance.

*If the committee does receive federal assistance, please answer questions 13 through 20. If the committee does not receive federal assistance, proceed directly to question 19.*

- 13. Does your committee prepare a Title VI plan? If yes, please provide a copy of the most recent plan.**

NA

- 14. Does your committee have a Title VI coordinator? If yes, please provide the Title VI coordinator's name and phone number and a brief description of his/her duties. If not, provide the name and phone number of the person responsible for dealing with Title VI issues.**

NA

- 15. To which state or federal agency (if any) does your committee report concerning Title VI? Please describe the information your committee submits to the state or federal government and/or provide a copy of the most recent report submitted.**

NA

- 16. Describe your committee's actions to ensure that committee staff and clients/program participants understand the requirements of Title VI.**

NA

- 17. Describe your committee's actions to ensure it is meeting Title VI requirements. Specifically, describe any committee monitoring or tracking activities related to Title VI, and how frequently these activities occur.**

NA

- 18. Please describe the committee's procedures for handling Title VI complaints. Has your committee received any Title VI-related complaints during the past two years? If yes, please describe each complaint, how each complaint was investigated, and how each complaint was resolved (or, if not yet resolved, the complaint's current status).**

NA

- 19. Please provide a breakdown of current committee staff by title, ethnicity, and gender.**

The Genetics Advisory Committee has no staff solely dedicated to its activities. Seven central office staff support the work of this committee.

<b>Title</b>	<b>Race/Ethnicity</b>	<b>Gender</b>
Program Director 1	Black	Female
Public Health Nursing Consultant 2	White	Female
Public Health Nursing	White	Female

Consultant 2		
RN 4	White	Female
RN 4	White	Female
RN 3	White	Female
Administrative Services Assistant 2	Black	Female
Administrative Services Assistant 2	White	Female

**20. Please list all committee contracts, detailing each contractor, the services provided, the amount of the contract, and the ethnicity of the contractor/business owner.**

**The Committee has no contracts for which it is directly responsible.**

## GENETICS ADVISORY COMMITTEE (T.C.A. Section 68-5-503)

Fifteen members appointed by the Commissioner for four year terms. The Committee shall be composed of one representative from each regional genetic center and each regional sickle cell center, five members at-large, and the Chief Medical Officer of the State. The Chief Medical Office shall serve as Chairman.

<u>MEMBERS</u>	<u>TITLE</u>	<u>REPRESENTATION</u>	<u>DATE</u>	
			<u>APPOINTED</u>	<u>EXPIRATION</u>
Bridget Kathleen McCabe, M.D., M.P.H. TN Department of Health Health Services Administration 4 <sup>th</sup> Floor, Cordell Hull Building 425 5 <sup>th</sup> Avenue North Nashville, Tennessee 37243	Member	Chief Medical Officer Designee	EX-OFFICIO	
Manoo Bhakta, M.D. T.C. Thompson Children's Hospital Department of Hematology/Oncology 910 Blackford Street Chattanooga, Tennessee 37403	Member	Sickle Cell Center	05-19-08	05-31-12
Ellen Clayton, M.D., J.D. Professor of Pediatrics Professor of Law 507A Light Hall Nashville, Tennessee 37232	Member	Member-At-Large Physician/Attorney	05-19-09	05-31-13
Karla J. Matteson, M.D., PhD U.T. Knoxville Developmental & Genetics Center 1930 Alcoa Highway, Suite 435 Knoxville, Tennessee 37920	Member	Genetic Center	05-19-08	05-31-12
Yvonne M. Carroll, RN, JD Director, Patient Services Dept of Hematology St. Jude Children's Research Hospital 262 Danny Thomas Place, MS800 Memphis, Tennessee 38105-2794	Member	Sickle Cell Center	05-10-11	5-31-15



# GENETICS ADVISORY COMMITTEE (cont'd.)

<u>MEMBERS</u>	<u>TITLE</u>	<u>REPRESENTATION</u>	<u>DATE APPOINTED</u>	<u>EXPIRATION</u>
John Phillips, III, M.D. Director Vanderbilt University Medical Center Division of Genetics, DD-2205 MCN Nashville, Tennessee 37232	Member	Genetic Center	05-18-10 (06-01-02)	05-31-14
Jack Rary, Ph.D. Director East Tennessee State University G-18A, Division of Genetics 325 State of Franklin Road Johnson City, Tennessee 37604	Member	Genetic Center	05-18-10 (06-01-02)	05-31-14
William Russell, M.D. Vanderbilt Children's Hospital, DOT Division of Pediatric Endocrinology 2200 Children's Way, Room 11136 Nashville, Tennessee 37232	Member	Member-At-Large Endocrinologist	05-10-11 (06-01-03)	05-31-15
Cathy Stevens, M.D. Director Genetics Program T.C. Thompson Children's Hospital 910 Blackford Street Chattanooga, Tennessee 38403	Member	Genetic Center	05-18-10 (06-01-02)	05-31-14
Jewell Ward, M.D., Ph.D. Director Division of Medical Genetics Department of Pediatrics UT Memphis 711 Jefferson Avenue Room 522 Memphis, Tennessee 38105	Member	Genetic Center	05-19-09	05-31-13

# GENETICS ADVISORY COMMITTEE (cont'd)

<u>MEMBERS</u>	<u>TITLE</u>	<u>REPRESENTATION</u>	<u>DATE APPOINTED</u>	<u>EXPIRATION</u>
Maria del Pilar Aguinaga, PhD., DLM Meharry Sickle Cell Center Meharry Medical College 1005 D. B. Todd Jr., Boulevard Nashville, Tennessee 37208	Member	Sickle Cell Center	05-18-10 (06-01-10)	05-31-14
Diana W. White U.T. Knoxville UT Genetics Center 1930 Alcoa Highway, Suite 435 Knoxville, Tennessee 37920	Member	Sickle Cell Center	05-19-08	05-31-12
Tonya Bowman 3716 Bakerstown Road Nashville, Tennessee 37211	Member	Member-At-Large Parent	04-23-09	04-30-13
William F. Walsh, MD Division of Neonatology Monroe Carell, Jr. Children's Hospital 2200 Children's Way, Suite 4523 Nashville, Tennessee 37232	Member	Member-At-Large Neonatologist	04-23-09	04-30-13
Dennis Clifton Stokes, MD, MPH Pediatric Pulmonary Medicine LeBonheur Children's Medical Center University of Tennessee Health Sciences Center 50 North Dunlap Memphis, Tennessee 38105	Member	Member-At-Large Pediatric Pulmonologist	04-23-09	04-30-13

May 2011

# **GENENTICS ADVISORY COMMITTEE**

(Updated May 10, 2011)

NAME	60+ YEARS	MINORITY	NON-MINORITY	MAN	WOMAN	GRAND DIVISION
Bhakta		*		*		East
Clayton	*		*		*	Middle
Matteson	*		*		*	East
McCabe			*		*	Middle
Carroll		*			*	West
Phillips	*		*	*		Middle
Rary			*	*		East
Russell	*		*	*		Middle
Stevens			*		*	East
Ward			*		*	West
Aguinaga		*			*	Middle
White	*		*		*	East
Bowman		*			*	Middle
Walsh			*	*		Middle
Stokes	*		*	*		West
<b>Totals</b>	<b>6</b>	<b>4</b>	<b>11</b>	<b>6</b>	<b>9</b>	<b>5-E 7-M 3-W</b>